IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kevin Woehr	
Assignee:	B. Braun Melsungen AG	
Title:	CATHETER INSERTION DEVICE	
Serial No.:	10/520,325	Filed: September 12, 2005
Examiner:	Anderson, Michael J.	Group Art Unit: 3767
Attorney Docket No.:	1131-14-PCT-PA-TD	

Mail Stop Appeal Brief – Patents
Board of Patent Appeals and Interferences
PO Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF

Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences the rejections of Claims 5-8 and 10-26 in the above-captioned patent application set forth in the final Office action mailed on March 30, 2009. Appellants filed a Notice of Appeal on September 1, 2009.

REAL PARTY IN INTEREST

The real party in interest in this appeal is the assignee of this application, B. Braun Melsungen, A.G.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF THE CLAIMS

Claims 1-26 are pending in the application. Claims 1-26 stand rejected in the final Office action mailed on March 30, 2009. Appellants hereby appeal Claims 5-8 and 10-26.

STATUS OF AMENDMENTS

Appellants have not submitted any Amendments subsequent to the final Office action. Therefore, the claims before the Board appear as shown in the Amendment filed on December 23, 2008, and as shown in the Claims Appendix attached hereto.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 5

Claim 5 recites a catheter insertion device comprising a hollow catheter hub having a catheter tube attached at a distal end thereof. Specification ("Spec."), para. 16, Fig. 1. Claim 5 further recites a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position. Spec., para. 17, Fig. 1. Claim 5 further recites a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub. Spec., paras. 17-18, Figs. 1, 2. A check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle. Spec., paras. 17-18, Figs. 1, 2. The check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube. Spec., para. 18, Fig. 2. The check valve comprises a valve disc, which has radial slits starting from a middle section of the valve disc. Spec., paras. 16, 18, Figs. 1, 2, 6. The check valve further comprises a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element. Spec., para. 17, Figs. 1, 3, 4.

Claim 6

Claim 6 recites the device according to claim 5, wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section and comprising two proximally extending legs defining the hollow space for receiving the needle guard therebetween. Spec., para. 17, Figs. 1, 3, 4.

Claim 10

Claim 10 recites a catheter insertion device comprising a catheter tube attached to an end of a catheter hub. Spec., para. 16, Fig. 1. The catheter tube comprises a lumen and the catheter hub comprises an interior cavity. Spec., para. 16, Fig. 1. Claim 10 further recites a needle

defining a needle axis attached to an end of a needle hub. Spec., para. 17, Fig. 1. The needle projects through the lumen of the catheter tube. Spec., para. 17, Fig. 1. Claim 10 further recites a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub and in mechanical communication with a movable valve actuating element for opening the valve. Spec., paras. 16, 17, Figs. 1, 3. The valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub. Spec., para. 18, Fig. 2. Claim 10 further recites a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve in a ready position. Spec., paras. 17, 18, Fig. 1.

Claim 11

Claim 11 recites a catheter insertion device comprising a catheter tube attached to an end of a catheter hub. Spec., para. 16, Fig. 1. The catheter tube comprises a lumen and the catheter hub comprises an interior cavity. Spec., para. 16, Fig. 1. Claim 11 further recites a needle defining a needle axis attached to an end of a needle hub. Spec., para. 17, Fig. 1. The needle projects through the lumen of the catheter tube and comprises an engaging section near a needle tip. Spec., paras. 17, 18, Figs. 1, 2. Claim 11 further recites a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub. Spec., paras. 16-18, Figs. 1-3. The valve comprises an opening and the needle projects through the opening. Spec., paras. 16, 17, Fig. 1. The valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub. Spec., para. 18, Fig. 2. Claim 11 further recites a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub. Spec., paras. 17, 18, Figs. 1, 2. A valve actuating element is slidably displaced in the interior cavity of the catheter hub for opening the valve. Spec., paras. 17, 19, Figs. 1, 3.

Claim 15

Claim 15 recites the catheter insertion device of claim 10, wherein the movable valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard. Spec., para. 17, Figs. 1, 4.

Claim 17

Claim 17 recites the catheter insertion device of claim 11, wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub. Spec., para. 23, Figs. 1, 2.

Claim 19

Claim 19 recites the catheter insertion device of claim 11, wherein the valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard. Spec., para. 17, Figs. 1, 4.

Claim 21

Claim 21 recites a catheter insertion device comprising a hollow catheter hub having a catheter tube attached at a distal end thereof. Spec., para. 16, Fig. 1. Claim 21 further recites a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position. Spec., para. 17, Fig. 1. Claim 21 further recites a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub. Spec., paras. 17-18, Figs. 1, 2. A check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle. Spec., paras. 17-18, Figs. 1, 2. The check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube. Spec., para. 18, Fig. 2. Claim 21 further recites a valve actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section, with two legs extending proximally therefrom, the two proximally extending legs defining a space therebetween configured for receiving the needle guard element. Spec., para. 17, Figs. 1, 4.

Claim 23

Claim 23 recites the catheter insertion device according to claim 10, wherein the movable valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs defining a space therebetween configured to receive the needle guard element. Spec., para. 17, Figs. 1, 4.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first issue before the Board is whether the subject matter of Claim 5 is unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,652,486 to Bialecki et al. ("Bialecki") in view of U.S. Patent No. 4,387,879 to Tauschinski.

The second issue before the Board is whether the subject matter of Claims 6 and 7 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The third issue before the Board is whether the subject matter of Claims 10, 13, 14 and 24 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The fourth issue before the Board is whether the subject matter of Claims 11, 16, 20, 25 and 26 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The fifth issue before the Board is whether the subject matter of Claim 15 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The sixth issue before the Board is whether the subject matter of Claim 17 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The seventh issue before the Board is whether the subject matter of Claim 19 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The eighth issue before the Board is whether the subject matter of Claims 21 and 22 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

The ninth and final issue before the Board is whether the subject matter of Claim 23 is unpatentable under 35 U.S.C. § 103(a) over Bialecki in view of Tauschinski.

APPELLANTS' ARGUMENTS

Rejection of Claim 5 over Bialecki in view of Tauschinski (Issue Number 1)

The Examiner rejected Claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 5 is allowable over Bialecki in view of Tauschinski.

Claim 5 recites a catheter insertion device comprising a hollow catheter hub having a catheter tube attached at a distal end thereof. Claim 5 further recites a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position. Claim 5 further recites a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an

engaging means formed near the needle tip when the hollow needle is removed from the catheter hub. A check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle. The check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube. The check valve comprises a valve disc, which has radial slits starting from a middle section of the valve disc. The check valve further comprises a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element.

By contrast, Bialecki discloses a catheter and introducer needle assembly. Bialecki, abstract. As shown in Figures 1 and 5 of Bialecki, reproduced below, the assembly 20 comprises a catheter assembly 22 and a needle assembly 24. The catheter assembly 22 includes a catheter 28 having a proximal end 31 fixedly attached to a catheter hub 30. The needle assembly 24 further includes a needle tip protector 26, which is disposed in the catheter hub 30 in the ready to use position. 3:21-27.[1]

FIG. 1

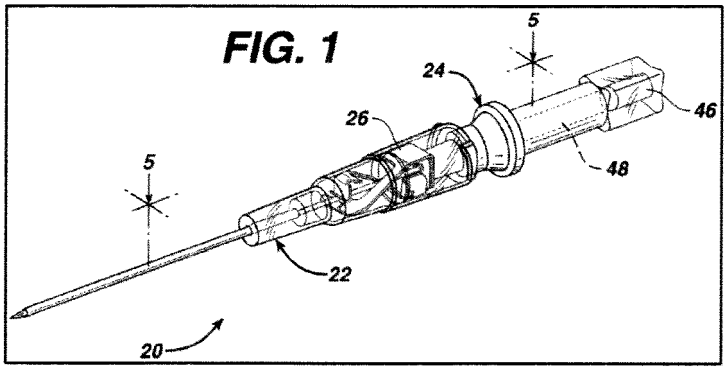
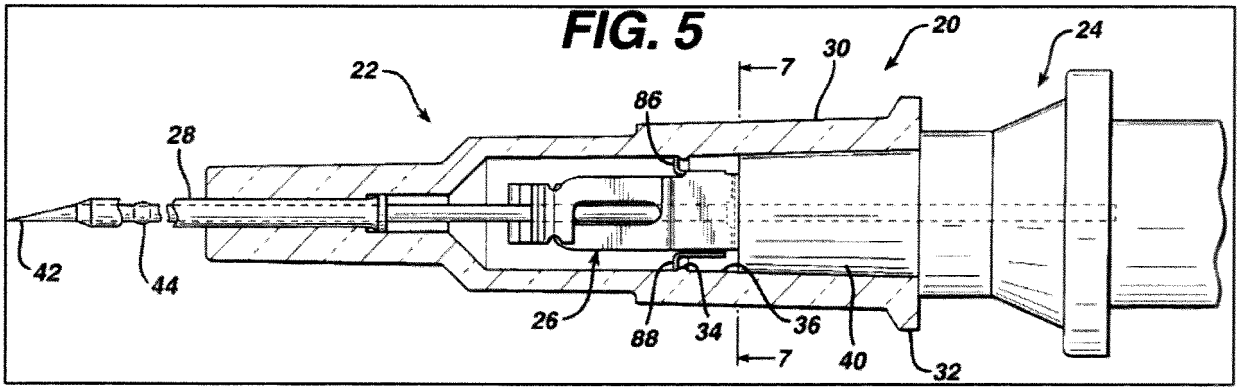
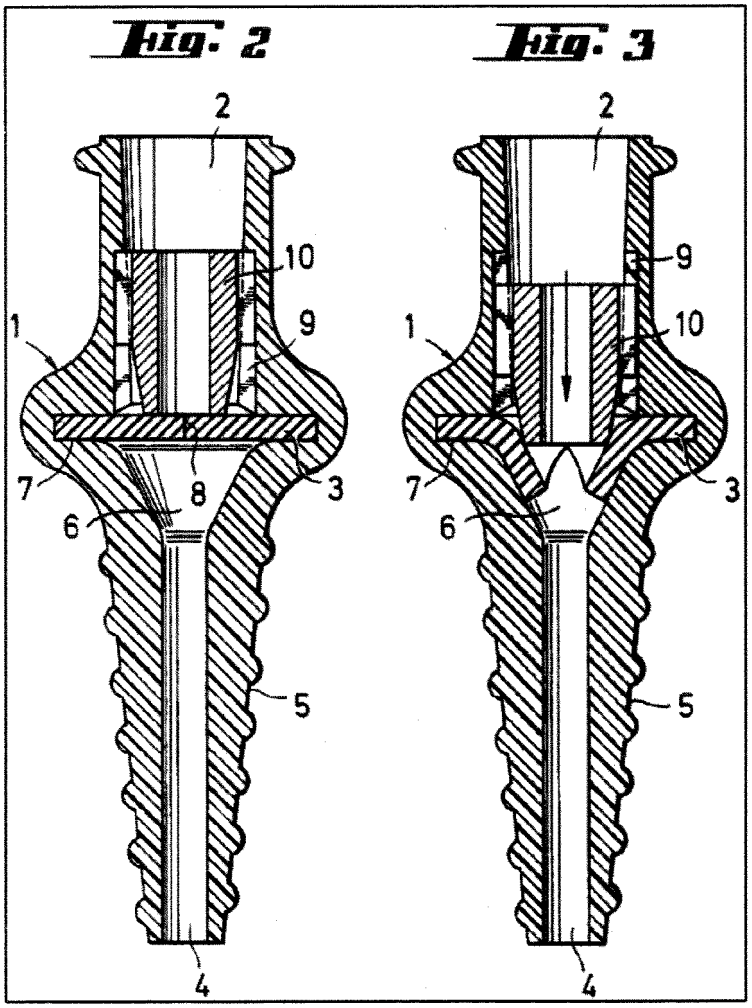


FIG. 5



Tauschinski discloses a self-sealing connector for use with plastic cannulas and vessel catheters. Tauschinski, title. As shown in Figures 2 and 3 of Tauschinski, reproduced below, the connector body 1 has a hollow conical portion 2 at its entrance, and a cylindrical passage 4 at its exit. A chamber 6 connects the interior of the hollow conical portion 2 to the passage 4. The

[1] Some references to Bialecki and Tauschinski herein follow the format of "column:line numbers." For example, the reference above to 3:21-27 refers to Bialecki at column 3, lines 21 through 27.



chamber 6 includes a disc 3 of elastic material having a central slit 8. 3:4-19. A member 10 is slidable within the hollow conical portion 2 and the chamber 6 to open and close the disc 3. 3:20-32.

The Examiner asserts that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a self sealing valve to block fluid flow." Final Office Action ("FOA"), p. 3. The Examiner provides this rationale for combining the teachings of Bialecki and Tauschinski in the rejection of Claim 1. The Examiner does not provide a separate rationale for combining the teachings of Bialecki and Tauschinski in the rejection of Claim 5. As detailed below, Appellants respectfully assert that there can be no supportable rationale for combining the teachings of Bialecki and Tauschinski as applied to Claim 5, because modifying Bialecki according to the teachings of Tauschinski in order to arrive at the device recited in Claim 5 would render Bialecki unsatisfactory for its intended purpose.

With reference to Figure 5 of Bialecki, reproduced below, the needle tip protector 26 includes first and second tabs 86, 88. 4:52-55. The tabs engage a raised annular ring, referred to as a rib 34, integral to and extending from the internal sidewall 36 of the catheter hub 30. The tabs 86, 88 and the rib 34 play an important role in securing the needle tip protector 26 in the catheter hub 30, as described below. 3:43-49.

FIG. 5

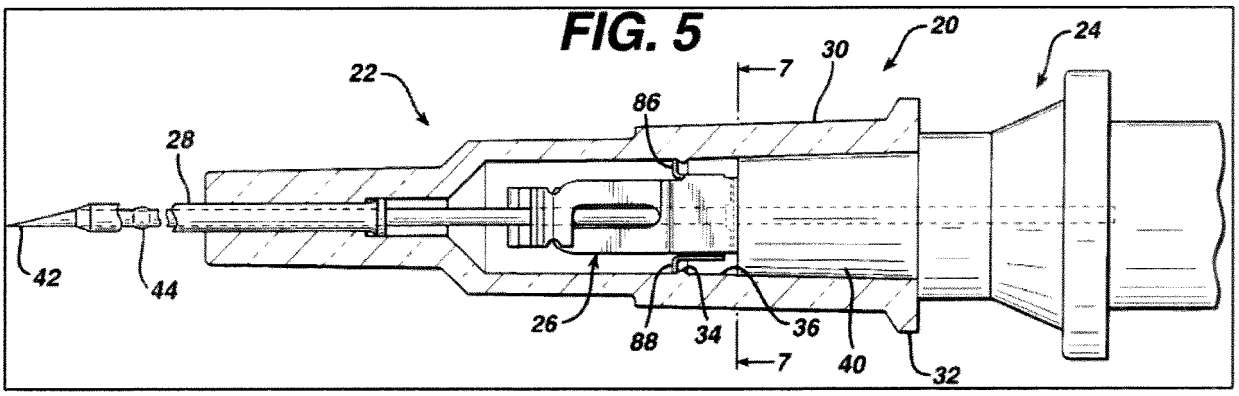


Figure 4 of Bialecki, reproduced below, is a detail view of the needle tip protector 26 from a proximal end. Figure 4 shows the needle tip protector 26 in an unconstrained state. In this state, a dimension across the tabs 86, 88 is indicated by the letter c. Figure 6 of Bialecki, reproduced below, is a detail view of the interface between the tabs 86, 88 and the rib 34. Figure 6 shows that the internal diameter of the catheter hub 30 at the rib 34 is indicated by the letter d. c is greater than d. Thus, when the needle tip protector 26 is positioned within the catheter hub 30 just distal of the rib 34, as in Figure 6, outward radial flexural forces in the tabs 86, 88 retain the needle tip protector 26 within the catheter hub 30. 5:39-42.

FIG. 4

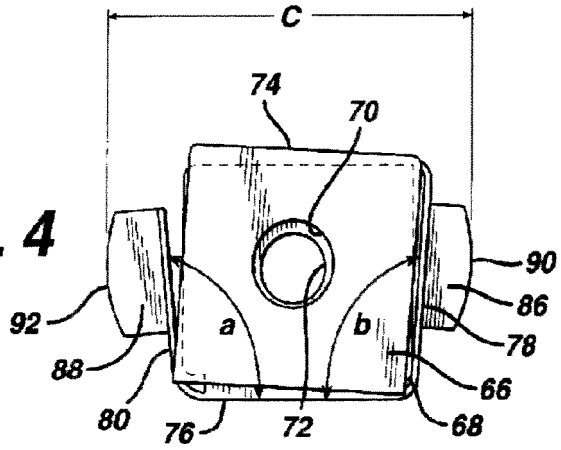
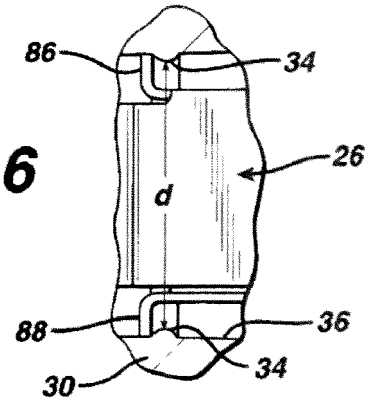


FIG. 6

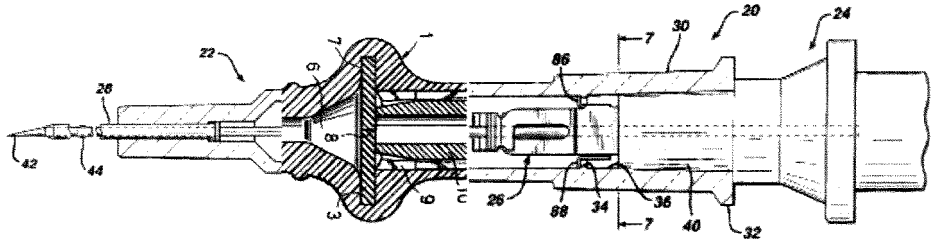


With reference to Figure 5, after a clinician has used the assembly 20 to emplace the catheter assembly 22 in a patient's blood vessel, he or she grasps the needle hub 40 and begins to withdraw the needle assembly 24 from the catheter assembly 22. During this process, the needle tip protector 26 remains secured inside the catheter hub 30 until a raised crimp 44 on the distal end of the needle 38 comes into contact with the second flange hole 72 (Figure 4) in the needle tip protector 26. Since the crimp 44 is larger than the second flange hole 72, continued proximal movement of the needle 38 carries the needle tip protector 26 proximal as well, forcing the first tab 86 and the

second tab 88 on the needle tip protector 26 against the rib 34 (Figure 6). The rib 34 forces the tabs 86, 88 to flex toward the center axis of the needle tip protector 26, permitting continued proximal movement past the rib 34 until the needle assembly 24 is removed entirely from the catheter assembly 22 with the needle tip protector 26 safely covering the sharp distal tip 42 of the needle 38. 5:61-6:16.

As the above discussion illustrates, the interaction of the rib 34 and the tabs 86, 88 is critical to proper operation of Bialecki's assembly 20. Without these components, there would be nothing to retain the needle tip protector 26 within the catheter hub 30 as the needle 38 is withdrawn. In the ready to use position of Figure 5, the needle tip protector 26 is disposed at a medial portion of the needle 38. Without the rib 34 and the tabs 86, 88, friction between the needle tip protector 26 and the needle 38 would draw the needle tip protector 26 proximally as the needle 38 is withdrawn, causing the needle tip protector 26 to remain at the medial portion of the needle 38 instead of sliding along the needle to cover the sharp distal tip 42.

The Examiner's proposed modification is shown below and identified as the "Proposed Combo" device. As further discussed below, the Proposed Combo device suffers from at least two glaring problems: (1) it lengthens the gap between the proximal edge of the catheter hub (near element 32) and the location of the opener 10 and of the valve 3, and (2) it retains the rib 34 for positioning the tip protector 26. Among other things, the length of the modified hub will render the combo device inoperable as no standard luer tip can reach into the catheter hub to activate the member 10 for opening the valve 3, as further discussed below. Still furthermore, the rib 34 will restrict the possibility that any standard luer tip can pass distally of the rib to reach the member 10 for opening the valve 3, also as further discussed below.



Proposed Combo Device

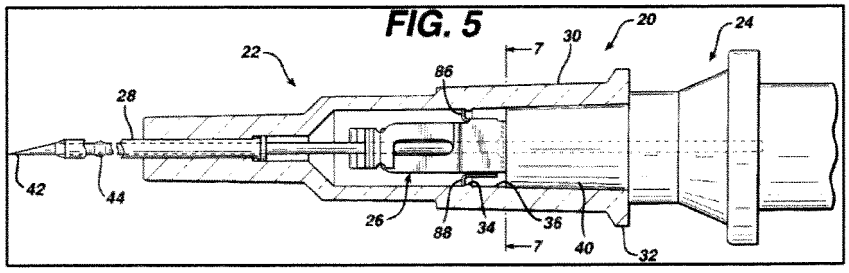
The Examiner's suggested modification of Bialecki would prevent the needle tip protector 26 from performing its intended function, because the rib 34 and the tabs 86, 88 would

no longer be able to retain the needle tip protector 26 within the catheter hub 30 as the needle 38 is withdrawn. The Examiner's suggested modification of Bialecki is to add the disc 3 and member 10 of Tauschinski into the space between the needle tip protector 26 and the catheter 28 as seen in Figure 5 of Bialecki and reproduced above. FOA, p. 3. But Claim 5 specifies that the valve actuating element has a hollow space for receiving the needle guard element. Thus, if Tauschinski's disc 3 and member 10 are added into the space between Bialecki's needle tip protector 26 and catheter 28 as the Examiner suggests, the needle tip protector 26 must be positioned within the central through bore of Tauschinski's member 10. This arrangement would interpose the sidewall of Tauschinski's member 10 between Bialecki's rib 34 and tabs 86, 88, preventing these components from retaining the needle tip protector 26 within the catheter hub 30 as the needle 38 is withdrawn. As described above, without the rib 34 and the tabs 86, 88, the needle tip protector 26 cannot properly cover the sharp needle tip 42 as the needle 38 is withdrawn.

In an obviousness rejection where one reference is to be modified by the teachings of another reference, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. M.P.E.P. § 2143.01(V). Here, interposing Tauschinski's member 10 between Bialecki's rib 34 and tabs 86, 88 would prevent these components from retaining the needle tip protector 26 within the catheter hub 30 as the needle 38 is withdrawn. The needle tip protector 26 would thus not be able to properly cover the sharp needle tip 42 as the needle 38 is withdrawn. Bialecki's catheter assembly 20 would thus be rendered unsatisfactory for its intended purpose. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Accordingly, there is no suggestion or motivation to modify Bialecki with Tauschinski as the Examiner suggests, and Claim 5 is allowable over Bialecki in view of Tauschinski for at least this reason.

Claim 5 is allowable over Bialecki in view of Tauschinski for at least one further reason. Again, the Examiner asserts that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a self sealing valve to block fluid flow." FOA, p. 3. To modify Bialecki as the

Examiner suggests, however, would require that Tauschinski's disc 3 and member 10 be positioned in the space between Bialecki's needle tip protector 26 and catheter 28 as reproduced above and referred to as the Proposed Combo device. However, with reference to Figure 5 of Bialecki and Figure 2 of Tauschinski, reproduced below, there is not enough room in the space between Bialecki's needle tip protector 26 and catheter 28 to accommodate Tauschinski's disc 3 and member 10.



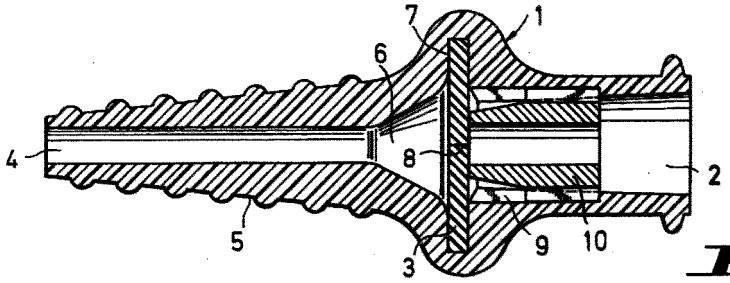


Fig. 2

Catheter assemblies are manufactured in sizes dictated by industry standards. Such standards are necessary to ensure that male and female connectors from different manufacturers will be compatible. More specifically, connectors from different manufacturers must fit together tightly enough to form fluid tight seals, as connectors are generally used to transfer liquids to and from a patient through various interconnected conduits. Thus, even though the drawings in Bialecki and Tauschinski may not be drawn to scale, in reality the inside diameter of each catheter hub is the same. Those of ordinary skill in the art appreciate that these components are manufactured according to industry standards. Accordingly, one of ordinary skill in the art upon viewing Figure 5 of Bialecki and Figure 2 of Tauschinski would conclude that the space between Bialecki's needle tip protector 26 and catheter 28 is not big enough to accommodate Tauschinski's disc 3 and member 10. Thus, in order to accommodate Tauschinski's disc 3 and member 10, Bialecki's catheter hub 30 would have to be lengthened. But such lengthening would render Bialecki's catheter assembly 20 inoperable.

Again, catheter assemblies are manufactured in standard sizes. Thus, a male Luer tip extends a standard distance from the distal end of a male Luer connector. For a device that combines Tauschinski's disc 3 and member 10 with Bialecki's catheter hub 30 to be operable, a male Luer tip must be able to reach the member 10 in order to urge it distally and thereby open the disc 3. But if Bialecki's catheter hub 30 were lengthened, the male tip would not be able to reach member 10, and the catheter assembly would be inoperable because the closed disc 3 would prevent fluid flow through the catheter. For at least this additional reason, then, Claim 5 is allowable over Bialecki in view of Tauschinski.

Claim 5 is allowable over Bialecki in view of Tauschinski for at least one further reason. Again, the Examiner's suggested modification of Bialecki is to add the disc 3 and member 10 of Tauschinski into the space between the needle tip protector 26 and the catheter 28 as seen in Figure 5 of Bialecki. FOA, p. 3 But if the disc 3 and member 10 of Tauschinski were added by lengthening the catheter hub of Bialecki then the rib 24 would stand in the way between member 10 for opening the valve and the standard male luer for pushing against the member 10. Thus even if the lengths could somehow be made within the Luer standards the rib 34 would block the male luer from pushing member 10 to open the slits in disc 3, and the proposed catheter assembly would be inoperable. For at least this additional reason, then, Claim 5 is allowable over Bialecki in view of Tauschinski.

Claim 5 is allowable over Bialecki in view of Tauschinski for at least one further reason. Again, the Examiner's suggested modification of Bialecki is to add the disc 3 and member 10 of Tauschinski into the space between the needle tip protector 26 and the catheter 28 as seen in Figure 5 of Bialecki. FOA, p. 3. But Claim 5 specifies that the valve actuating element has a hollow space for receiving the needle guard element. Thus, if Tauschinski's disc 3 and member 10 are added into the space between Bialecki's needle tip protector 26 and catheter 28 as the Examiner suggests, the needle tip protector 26 must be positioned within the central through bore of Tauschinski's member 10. For the reasons outlined below, however, the needle tip protector 26 cannot be positioned within the central through bore of Tauschinski's member 10.

As discussed above, catheter assemblies are manufactured in sizes dictated by industry standards. Thus, even though the drawings in Bialecki and Tauschinski may not be drawn to

scale, in reality the inside diameter of each catheter hub is the same. Those of ordinary skill in the art appreciate that these components are manufactured according to industry standards. Accordingly, one of ordinary skill in the art upon viewing Figure 5 of Bialecki and Figure 2 of Tauschinski would conclude that the central bore of the member 10 of Tauschinski is too narrow to accommodate the needle tip protector 26 of Bialecki. This conclusion can be drawn from the fact that the member 10 must have thick enough sidewalls that it will not collapse when urged distally by a male Luer tip pushing it from the proximal side. If the member 10 were to collapse, it would not be effective for its intended purpose, which is to open the disc 3. Since the space inside a standard catheter hub is already very narrow, further narrowing that space with the thick sidewalls of the member 10 leaves inadequate room for the structure of the needle tip protector 26. For at least this additional reason, then, Claim 5 is allowable over Bialecki in view of Tauschinski.

Furthermore, in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983) (emphasis added); MPEP 2141.02(I). Distilling an invention down to a "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 3030 (Fed. Cir. 1983); MPEP 2141.02(II). As held by the Board of Patent Appeals and Interferences in *Ex parte* Wada and Murphy (Appeal No. 2007-3733, decided January 14, 2008), "[w]hen determining whether a claim is obvious, an examiner must make "a searching of the claimed invention - *including all its limitations* - with the teaching of the prior art. *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)" (emphasis added). Because Bialecki does not teach a device that is capable of the suggested modification, the Examiner's use of Bialecki and Tauschinski is clearly a distilling exercise since neither reference hints or suggests the proposed modification.

Since the combination of Bialecki and Tauschinski is defective for all of the reasons provided above, Appellants respectfully submit that Claim 5 is allowable over Bialecki in view of Tauschinski. Claims 6, 7 and 8, which depend from Claim 5, recite additional features of

particular advantage and utility. Moreover, these claims are allowable for substantially the same reasons presented above. Accordingly, Appellants respectfully request that the Board reverse these rejections.

Rejections of Claims 6 and 7 over Bialecki in view of Tauschinski (Issue Number 2)

The Examiner rejected Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 6 is allowable over Bialecki in view of Tauschinski.

Claim 6 recites the device according to claim 5, wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section and comprising two proximally extending legs defining the hollow space for receiving the needle guard therebetween. Bialecki in view of Tauschinski does not teach or suggest a valve actuating element having all of the limitations recited in Claim 6.

The Examiner asserts that Tauschinski's element 10 "is formed as a hollow cylinder (10) with a truncated cone-shaped distal end section and comprising two proximally extending legs (figure 3 shows the hollow cone shaped actuating element) defining the hollow space for receiving the needle guard therebetween." FOA, p. 4. Appellants respectfully disagree. Figure 2 of Tauschinski clearly represents the member 10 as being cylindrical, as evidenced by the cross-hatching in the cylinder sidewall and the longitudinal shade lines in the interior of the cylinder. Further, column 3, lines 25-27 of Tauschinski describe the member 10 as being cylindrical. The cylindrical member 10 does not include "two proximally extending legs defining the hollow space for receiving the needle guard therebetween," as recited in Claim 6. For at least this reason, then, Claim 6 is allowable over Bialecki in view of Tauschinski.

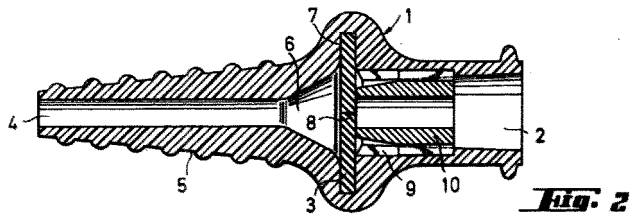


Fig. 2

Further, as described above with respect to Claim 5, the proposed combination of Bialecki and Tauschinski would render the prior art unsatisfactory for its intended purpose. Bialecki and Tauschinski thus cannot be combined. For at least this additional reason, then, Claim 6 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 6 is allowable over Bialecki in view of Tauschinski. Claim 7, which depends from Claim 6, recites additional features of particular advantage and utility. Moreover, Claim 7 is allowable for substantially the same reasons presented above. Accordingly, Appellants respectfully request that the Board reverse these rejections.

Rejections of Claims 10, 13, 14 and 24 over Bialecki in view of Tauschinski (Issue Number 3)

The Examiner rejected Claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 10 is allowable over Bialecki in view of Tauschinski.

Claim 10 recites a catheter insertion device. The device comprises a catheter tube attached to an end of a catheter hub. The catheter tube comprises a lumen and the catheter hub comprises an interior cavity. The device further comprises a needle defining a needle axis

attached to an end of a needle hub. The needle projects through the lumen of the catheter tube. The device further comprises a valve for regulating fluid flow. The valve is positioned inside the interior cavity of the catheter hub and is in mechanical communication with a movable valve actuating element for opening the valve. The valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub. The device further comprises a needle guard element comprising two needle guard arms crossing the needle axis of the needle. The needle guard element is positioned inside the catheter hub adjacent the valve in a ready position.

By contrast, Bialecki discloses a catheter and introducer needle assembly, as described above with respect to Claim 5 and as shown in Figure 5 below. Tauschinski discloses a self-sealing connector for use with plastic cannulas and vessel catheters, as described above with respect to Claim 5 and as shown in Figures 2 and 3 below.

FIG. 5

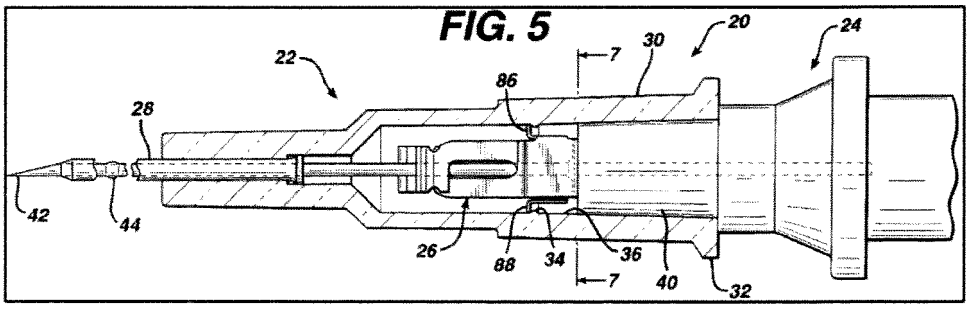


Fig. 2

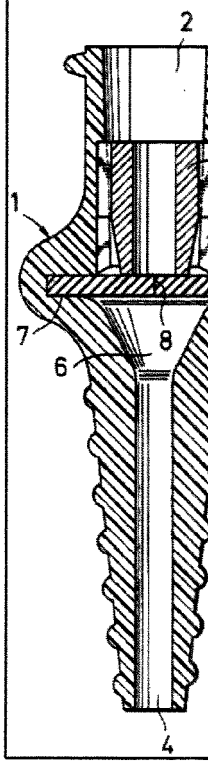
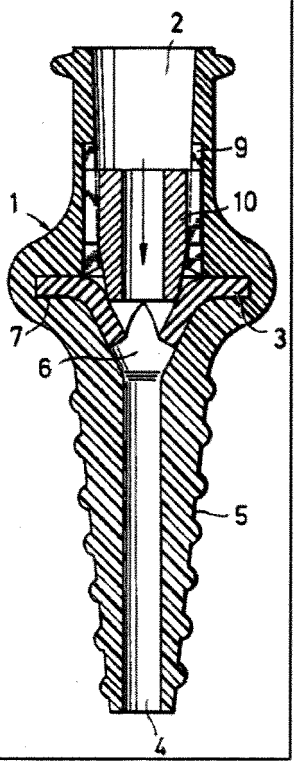


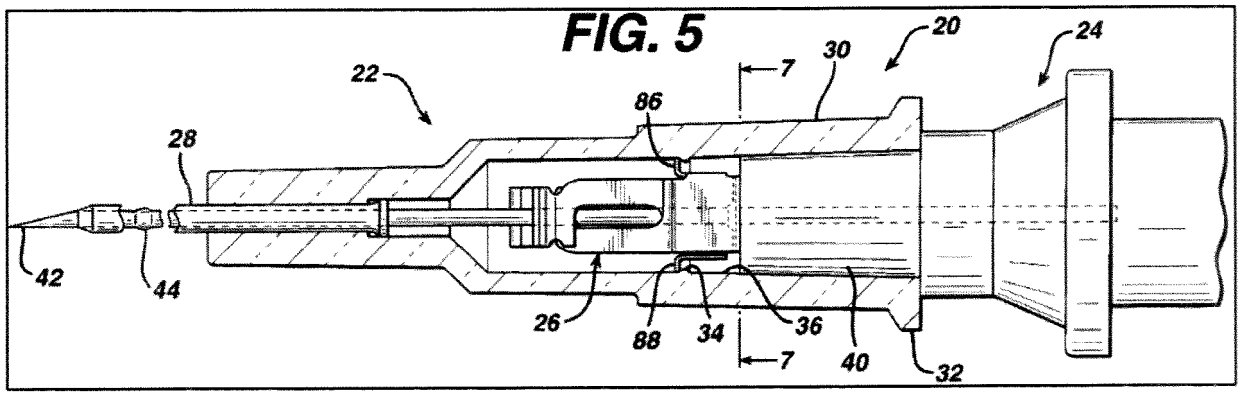
Fig. 3



In rejecting Claim 10, the Examiner refers to the previous rejections of Claims 1, 5 and 9, and then simply recites the language of Claim 10. Thus, it is not entirely clear what portions of Bialecki and Tauschinski the Examiner asserts as showing the limitations of Claim 10. Nevertheless, as detailed below, Appellants respectfully assert that there can be no supportable rationale for combining the teachings of Bialecki and Tauschinski as applied to Claim 10, because modifying Bialecki according to the teachings of Tauschinski would render Bialecki

unsatisfactory for its intended purpose.

Since the Examiner refers back to the rejections of Claims 1, 5 and 9 in the rejection of Claim 10, Appellants have presumed for purposes of the present appeal that the Examiner's rejection of Claim 10 is based upon modifying Bialecki's catheter assembly by adding Tauschinski's disc 3 and member 10 in the space between the needle tip protector 26 and the catheter 28, according to the rejection of Claim 1. However, with reference to Figure 5 of Bialecki and Figure 2 of Tauschinski, reproduced below, there is not enough room in the space between Bialecki's needle tip protector 26 and catheter 28 to accommodate Tauschinski's disc 3 and member 10.



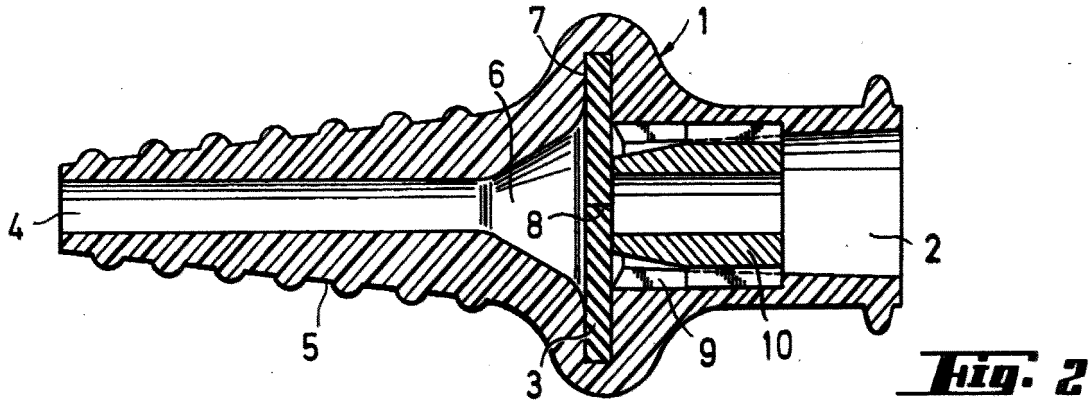


Fig. 2

Catheter assemblies are manufactured in sizes dictated by industry standards. Such standards are necessary to ensure that male and female connectors from different manufacturers will be compatible. More specifically, connectors from different manufacturers must fit together tightly enough to form fluid tight seals, as connectors are generally used to transfer liquids to and from a patient through various interconnected conduits. Thus, even though the drawings in Bialecki and Tauschinski may not be drawn to scale, in reality the inside diameter of each

catheter hub is the same. Those of ordinary skill in the art appreciate that these components are manufactured according to industry standards. Accordingly, one of ordinary skill in the art upon viewing Figure 5 of Bialecki and Figure 2 of Tauschinski would conclude that the space between Bialecki's needle tip protector 26 and catheter 28 is not big enough to accommodate Tauschinski's disc 3 and member 10. Thus, in order to accommodate Tauschinski's disc 3 and member 10, Bialecki's catheter hub 30 would have to be lengthened. But such lengthening would render Bialecki's catheter assembly 20 inoperable.

Again, catheter assemblies are manufactured in standard sizes. Thus, a male Luer tip extends a standard distance from the distal end of a male Luer connector. For a device that combines Tauschinski's disc 3 and member 10 with Bialecki's catheter hub 30 to be operable, a male Luer tip must be able to reach the member 10 in order to urge it distally and thereby open the disc 3. But if Bialecki's catheter hub 30 were lengthened, the male tip would not be able to reach member 10, and the catheter assembly would be inoperable because the closed disc 3 would prevent fluid flow through the catheter. In an obviousness rejection where one reference is to be modified by the teachings of another reference, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. M.P.E.P. § 2143.01(V). For at least this reason, then, Claim 10 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 10 is allowable over Bialecki in view of Tauschinski. Claims 13, 14 and 24, which depend from Claim 10, recite additional features of particular advantage and utility. Moreover, these claims are allowable for substantially the same reasons presented above. Accordingly, Appellants respectfully request that the Board reverse these rejections.

Rejection of Claims 11, 16, 20, 25 and 26 over Bialecki in view of Tauschinski (Issue Number 4)

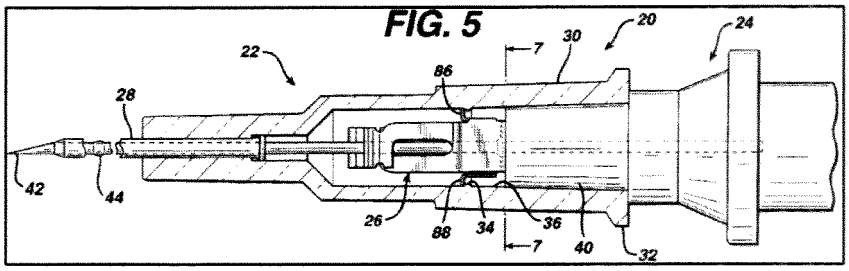
The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 11 is allowable over Bialecki in view of Tauschinski.

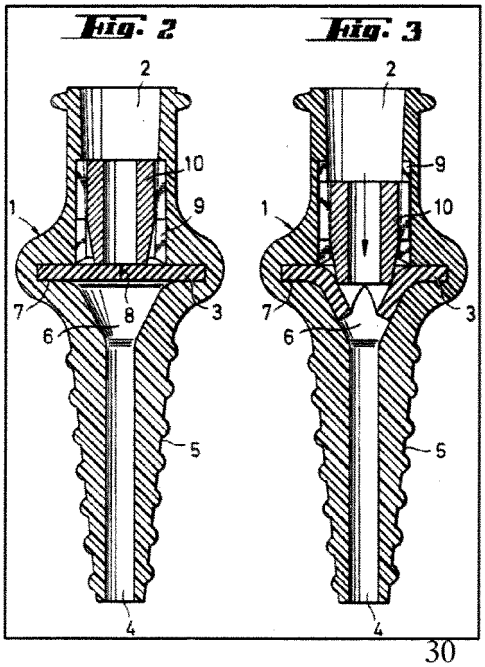
Claim 11 recites a catheter insertion device. The device comprises a catheter tube attached to an end of a catheter hub. The catheter tube comprises a lumen and the catheter hub comprises an interior cavity. The device further comprises a needle defining a needle axis

attached to an end of a needle hub. The needle projects through the lumen of the catheter tube and comprises an engaging section near a needle tip. The device further comprises a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub. The valve comprises an opening and the needle projects through the opening. The valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub. The device further comprises a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub. A valve actuating element is slidably displaced in the interior cavity of the catheter hub for opening the valve.

By contrast, Bialecki discloses a catheter and introducer needle assembly, as described above with respect to Claim 5 and as shown in Figure 5 below. Tauschinski discloses a self-sealing connector for use with plastic cannulas and vessel catheters, as described above with respect to Claim 5 and as shown in Figures 2 and 3 below.

FIG. 5

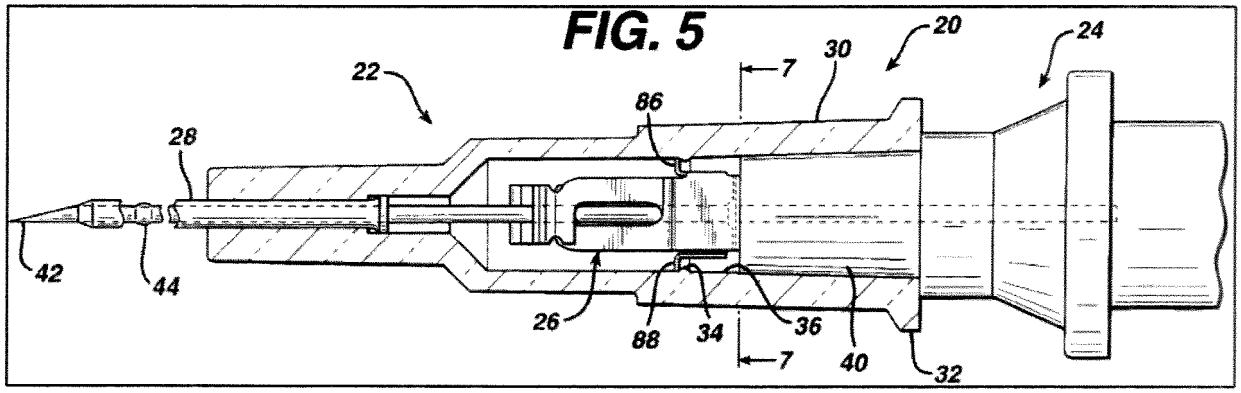




In rejecting Claim 11, the Examiner refers to the previous rejections of Claims 1, 5 and 9, and then simply recites the language of Claim 11. Thus, it is not entirely clear what portions of Bialecki and Tauschinski the Examiner asserts as showing the limitations of Claim 11. Nevertheless, as detailed below, Appellants respectfully assert that there can be no supportable rationale for combining the teachings of Bialecki and Tauschinski as applied to Claim 11, because modifying Bialecki according to the teachings of Tauschinski would render Bialecki unsatisfactory for its intended purpose.

Since the Examiner refers back to the rejections of Claims 1, 5 and 9 in the rejection of Claim 11, Appellants have presumed for purposes of the present appeal that the Examiner's rejection of Claim 11 is

based upon modifying Bialecki's catheter assembly by adding Tauschinski's disc 3 and member 10 in the space between the needle tip protector 26 and the catheter 28, according to the rejection of Claim 1. However, with reference to Figure 5 of Bialecki and Figure 2 of Tauschinski, reproduced below, there is not enough room in the space between Bialecki's needle tip protector 26 and catheter 28 to accommodate Tauschinski's disc 3 and member 10.



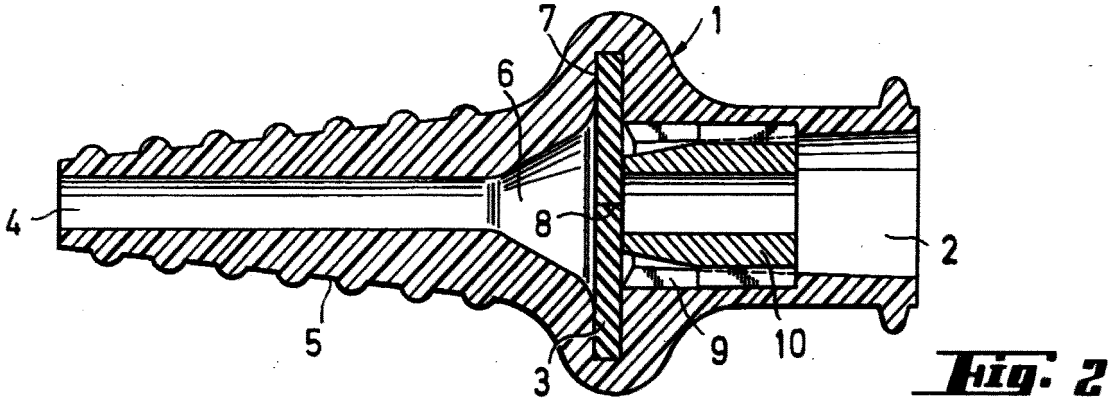


Fig. 2

Catheter assemblies are manufactured in sizes dictated by industry standards. Such standards are necessary to ensure that male and female connectors from different manufacturers will be compatible. More specifically, connectors from different manufacturers must fit together tightly enough to form fluid tight seals, as connectors are generally used to transfer liquids to and from a patient through various interconnected conduits. Thus, even though the drawings in Bialecki and Tauschinski may not be drawn to scale, in reality the inside diameter of each catheter hub is the same. Those of ordinary skill in the art appreciate that these components are manufactured according to industry standards. Accordingly, one of ordinary skill in the art upon viewing Figure 5 of Bialecki and Figure 2 of Tauschinski would conclude that the space between Bialecki's needle tip protector 26 and catheter 28 is not big enough to accommodate

Tauschinski's disc 3 and member 10. Thus, in order to accommodate Tauschinski's disc 3 and member 10, Bialecki's catheter hub 30 would have to be lengthened. But such lengthening would render Bialecki's catheter assembly 20 inoperable.

Again, catheter assemblies are manufactured in standard sizes. Thus, a male Luer tip extends a standard distance from the distal end of a male Luer connector. For a device that combines Tauschinski's disc 3 and member 10 with Bialecki's catheter hub 30 to be operable, a male Luer tip must be able to reach the member 10 in order to urge it distally and thereby open the disc 3. But if Bialecki's catheter hub 30 were lengthened, the male tip would not be able to reach member 10, and the catheter assembly would be inoperable because the closed disc 3 would prevent fluid flow through the catheter. In an obviousness rejection where one reference is to be modified by the teachings of another reference, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. M.P.E.P. § 2143.01(V). For at least this reason, then, Claim 11 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 11 is allowable over Bialecki in view of Tauschinski. Claims 16, 20, 25 and 26, which depend from Claim 11, recite additional features of particular advantage and utility. Moreover, these claims are allowable for substantially the same reasons presented above. Accordingly, Appellants respectfully request that the Board reverse these rejections.

Rejection of Claim 15 over Bialecki in view of Tauschinski (Issue Number 5)

The Examiner rejected Claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 15 is allowable over Bialecki in view of Tauschinski.

Claim 15 recites the catheter insertion device of claim 10, wherein the movable valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard. Bialecki in view of Tauschinski does not teach or suggest a valve actuating element having all of the limitations recited in Claim 15.

The Examiner asserts that "Tauschinski further discloses wherein the movable valve actuating element comprises two leg sections (figures 2 and 3 the cone (10) is hollow) comprising a space therebetween for accommodating the needle guard." FOA, pp. 6-7.

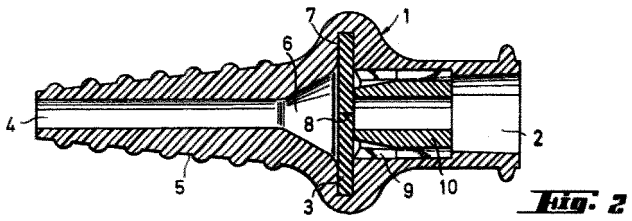


Fig. 2

Appellants respectfully disagree. Figure 2 of Tauschinski clearly represents the member 10 as being cylindrical, as evidenced by the cross-hatching in the cylinder sidewall and the longitudinal shade lines in the interior of the cylinder. Further, column 3, lines 25-27 of Tauschinski describe the member 10 as being cylindrical. The Examiner notes that the member 10 is hollow, but Appellants do not see how this point is relevant. The cylindrical member 10 does not include "two leg sections comprising a space therebetween for accommodating the needle guard," as recited in Claim 15. For at least this reason, then, Claim 15 is allowable over Bialecki in view of Tauschinski.

Further, as described above with respect to Claim 5, the proposed combination of Bialecki and Tauschinski would render the prior art unsatisfactory for its intended purpose. Bialecki and Tauschinski thus cannot be combined. For at least this additional reason, then, Claim 15 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 15 is allowable over Bialecki in view of Tauschinski. Accordingly, Appellants respectfully request that the Board reverse this rejection.

Rejection of Claim 17 over Bialecki in view of Tauschinski (Issue Number 6)

The Examiner rejected Claim 17 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 17 is allowable over Bialecki in view of Tauschinski.

Claim 17 recites the catheter insertion device of claim 11, wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub. Figure 1 of the present application, a portion of which is reproduced at left, shows an example of the needle guard 13

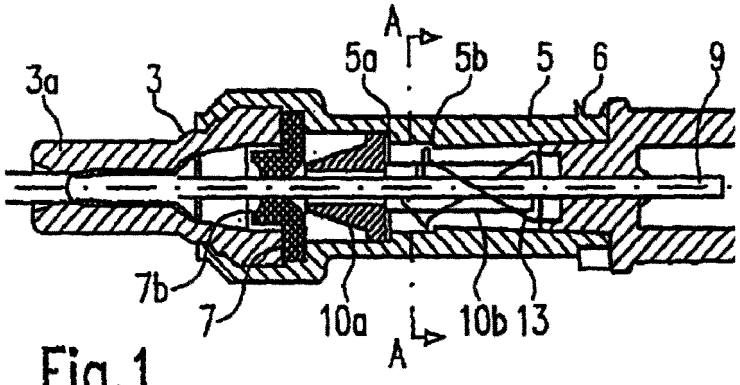


Fig.1

having an apex abutting a shoulder 5b located on the interior surface of the catheter hub 5.

In Bialecki, by contrast, the apexes on the first and second beams 96, 100 do not abut any shoulder located on the interior surface of the catheter hub 30. With reference to Figure 3 of Bialecki, reproduced below, the apexes on the first and second beams 96, 100 occur near the distal end of each, as indicated with the labels "APEX." Bialecki does not specify whether these apexes abut the interior surface of the catheter hub 30. However, with reference to Figure 1 of Bialecki, also reproduced below, the apexes either abut a smooth interior surface portion of the catheter hub, or don't abut the catheter hub at all. Accordingly, Bialecki does not teach or suggest "wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub," as recited in Claim 17.

FIG. 3

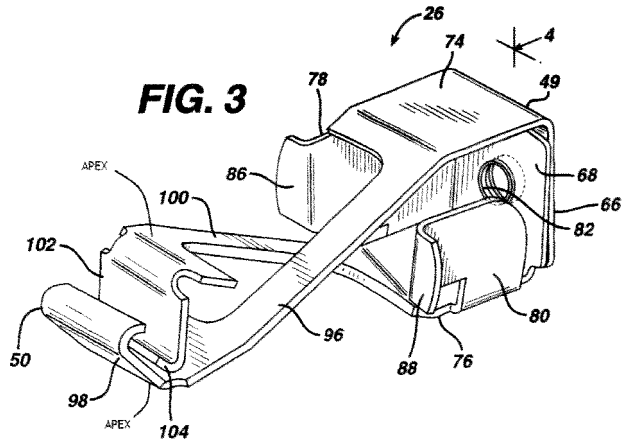
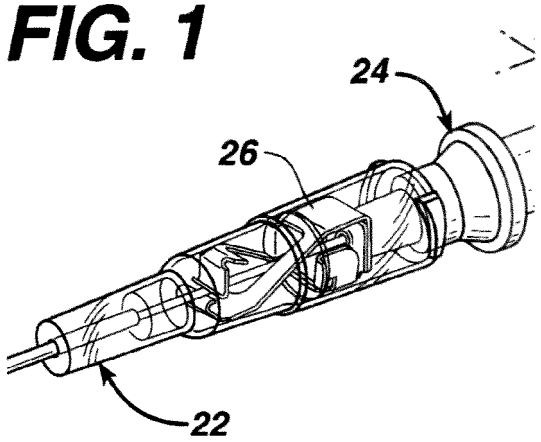


FIG. 1



Tauschinski does not teach or suggest any needle guard at all. Since neither Bialecki nor Tauschinski teaches or suggests "wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub," their combination cannot possibly teach or suggest this limitation of Claim 17. Since Bialecki in view of Tauschinski is defective for at least this reason, Appellants respectfully submit that Claim 17 is allowable over Bialecki in view of Tauschinski.

Further, as described above with respect to Claim 5, the proposed combination of Bialecki and Tauschinski would render the prior art unsatisfactory for its intended purpose. Bialecki and Tauschinski thus cannot be combined. For at least this additional reason, then, Claim 17 is allowable over Bialecki in view of Tauschinski. Accordingly, Appellants respectfully request that the Board reverse this rejection.

Rejection of Claim 19 over Bialecki in view of Tauschinski (Issue Number 7)

The Examiner rejected Claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 19 is allowable over Bialecki in view of Tauschinski.

Claim 19 recites the catheter insertion device of claim 11, wherein the valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard. Bialecki in view of Tauschinski does not teach or suggest a valve actuating element having all of the limitations recited in Claim 19.

The Examiner asserts that "Tauschinski further discloses wherein the valve actuating element comprises two leg sections (figures 2 and 3 the cone (10) is hollow) comprising a space therebetween for accommodating the needle guard." FOA, p. 7. Appellants respectfully disagree. Figure 2 of Tauschinski clearly represents the member 10 as being cylindrical, as evidenced by the cross-hatching in the cylinder sidewall and the longitudinal shade lines in the interior of the cylinder. Further, column 3, lines 25-27 of Tauschinski describe the member 10 as being cylindrical. The Examiner notes that the member 10 is hollow, but Appellants do not see how this point is relevant. The cylindrical member 10 does not include "two leg sections comprising a space therebetween for accommodating the needle guard," as recited in Claim 19. For at least this reason, then, Claim 19 is allowable over Bialecki in view of Tauschinski.

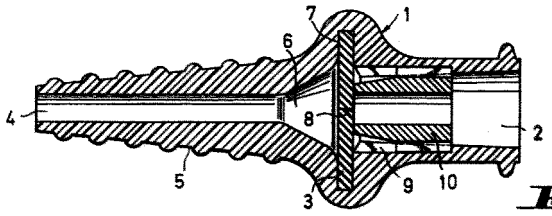


Fig. 2

Further, as described above with respect to Claim 5, the proposed combination of Bialecki and Tauschinski would render the prior art unsatisfactory for its intended purpose. Bialecki and Tauschinski thus cannot be combined. For at least this additional reason, then, Claim 19 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 19 is allowable over Bialecki in view of Tauschinski. Accordingly, Appellants respectfully request that the Board reverse this rejection.

Rejections of Claims 21 and 22 over Bialecki in view of Tauschinski (Issue Number 8)

The Examiner rejected Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 21 is allowable over Bialecki in view of Tauschinski.

Claim 21 recites the device according to claim 1, further comprising a valve actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section, with two legs extending proximally therefrom, the two proximally extending legs defining a space therebetween configured for receiving the needle guard element. Bialecki in view of Tauschinski does not teach or suggest a valve actuating element having all of the limitations recited in Claim 21.

The Examiner asserts that "Tauschinski further discloses it further comprising a valve actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section, with two legs extending proximally therefrom, the two proximally extending legs (figures 2 and 3 the cone (10) is hollow) defining a space therebetween configured for receiving the needle guard element." FOA, pp. 7-8. Appellants respectfully disagree. Figure 2 of Tauschinski

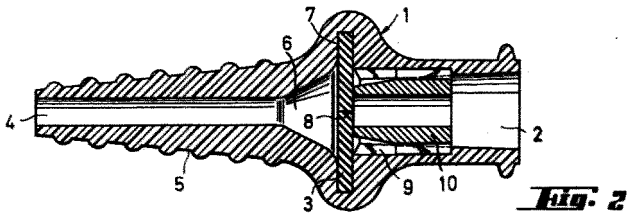


Fig. 2

clearly represents the member 10 as being cylindrical, as evidenced by the cross-hatching in the cylinder sidewall and the longitudinal shade lines in the interior of the cylinder. Further, column 3, lines 25-27 of Tauschinski describe the member 10 as being cylindrical. The cylindrical member 10 does not include "a hollow cylinder with a truncated cone-shaped distal end section, with two legs extending proximally therefrom, the two proximally extending legs defining a space therebetween configured for receiving the needle guard element," as recited in Claim 21. For at least this reason, then, Claim 21 is allowable over Bialecki in view of Tauschinski.

Further, as described above with respect to Claim 5, the proposed combination of Bialecki and Tauschinski would render the prior art unsatisfactory for its intended purpose. Bialecki and Tauschinski thus cannot be combined. For at least this additional reason, then, Claim 21 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 21 is allowable over Bialecki in view of

Tauschinski. Claim 22, which depends from Claim 21, recites additional features of particular advantage and utility. Moreover, Claim 22 is allowable for substantially the same reasons presented above. Accordingly, Appellants respectfully request that the Board reverse these rejections.

Rejection of Claim 23 over Bialecki in view of Tauschinski (Issue Number 9)

The Examiner rejected Claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Bialecki in view of Tauschinski. For the reasons set forth below, Appellants respectfully submit that Claim 23 is allowable over Bialecki in view of Tauschinski.

Claim 23 recites the catheter insertion device according to claim 10, wherein the movable valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs defining a space therebetween configured to receive the needle guard element. Bialecki in view of Tauschinski does not teach or suggest a valve actuating element having all of the limitations recited in Claim 23.

The Examiner asserts that "Tauschinski further discloses wherein the movable valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs (figures 2 and 3 the cone (10) is hollow) defining a space therebetween configured to receive the needle guard element." FOA, p. 8. Appellants respectfully disagree. Figure 2 of Tauschinski clearly represents the member 10 as being cylindrical, as evidenced by the cross-hatching in the cylinder sidewall and the longitudinal shade lines in the interior of the cylinder. Further, column 3, lines 25-27 of Tauschinski describe the member 10 as being cylindrical. The cylindrical member 10 does not include "two proximally extending legs defining a space therebetween configured to receive the needle guard element," as recited in Claim 23. For at least this reason, then, Claim 23 is allowable over Bialecki in view of Tauschinski.

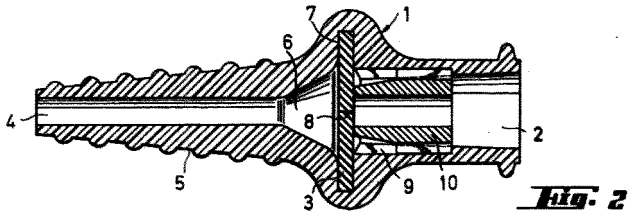


Fig. 2

Further, as described above with respect to Claim 5, the proposed combination of Bialecki and Tauschinski would render the prior art unsatisfactory for its intended purpose.

Bialecki and Tauschinski thus cannot be combined. For at least this additional reason, then, Claim 23 is allowable over Bialecki in view of Tauschinski.

Since the combination of Bialecki and Tauschinski is defective for the reasons provided above, Appellants respectfully submit that Claim 23 is allowable over Bialecki in view of Tauschinski. Accordingly, Appellants respectfully request that the Board reverse this rejection.

CONCLUSION

In view of the foregoing, Appellants respectfully submit that the Examiner's rejections of Claims 5-8 and 10-26 under § 103(a) are not well founded. Appellants therefore respectfully request that the Board reverse the Examiner's rejections.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1159.

Date: October 28, 2009

Respectfully submitted,

Scott Loras Murray
Reg. No.: 53,360
Attorney for Appellants
Tel.: (949) 955-1920

CLAIMS APPENDIX

WHAT IS CLAIMED IS:

1. (Previously Presented) A catheter insertion device comprising

a hollow catheter hub having a catheter tube attached at a distal end thereof,

a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position,

a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub,

wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle, and wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube.

2. (Original) The device according to claim 1, wherein the catheter hub comprises a distal hub element and a proximal hub element, and the check valve is held between the distal hub element and the proximal hub element, which are joined to one another.

3. (Original) The device according to claim 1, wherein the check valve has a plurality of radially elastically expandable valve flaps configured to be moved into an open position by fluid pressure generated from a syringe.

4. (Original) The device according to claim 1, wherein the catheter hub comprises an inner circumference and a radial projection projecting radially from the inner circumference, which is configured to engage with the needle guard element in the ready position.

5. (Previously Presented) The device according to claim 1, wherein the check valve comprises a valve disc, which has radial slits starting from a middle section of the valve disc, and a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element.

6. (Previously Presented) The device according to claim 5, wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section and comprising two proximally extending legs defining the hollow space for receiving the needle guard therebetween.

7. (Previously Presented) The device according to claim 6, wherein the hollow cylindrical valve actuating element comprises an inner circumference and a radial projection.

8. (Original) The device according to claim 5, wherein the valve actuating element has a truncated cone-shaped abutting section.

9. (Original) The device according to claim 1, wherein the needle guard element is formed as a spring clip which has diametrically opposite spring arms starting from a rear wall provided with a bore, wherein bent end sections of the spring arms overlap and block the needle tip when the engaging means of the needle comes to abut on the rear wall.

10. (Previously Presented) A catheter insertion device comprising:

a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity;

a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube;

a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub and in mechanical communication with a movable valve actuating element for opening the valve, and wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub; and

a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve in a ready position.

11. (Previously Presented) A catheter insertion device comprising:

a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity;

a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube and comprising an engaging section near a needle tip;

a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening, and wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub;

a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub; and

wherein a valve actuating element is slidably displaced in the interior cavity of the catheter hub for opening the valve.

12. (Previously Presented) The catheter insertion device of claim 10, wherein the two needle guard arms cross one another.

13. (Previously Presented) The catheter insertion device of claim 10, wherein the needle guard element comprises a proximal wall comprising an opening having the needle passing therethrough.

14. (Previously Presented) The catheter insertion device of claim 10, wherein the valve is a disc having at least one slit formed therein.

15. (Previously Presented) The catheter insertion device of claim 10, wherein the movable valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard.

16. (Previously Presented) The catheter insertion device of claim 11, wherein the engaging section is crimp.

17. (Previously Presented) The catheter insertion device of claim 11, wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub.

18. (Previously Presented) The catheter insertion device of claim 11, wherein the needle guard comprises two arms that intersect one another.

19. (Previously Presented) The catheter insertion device of claim 11, wherein the valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard.

20. (Previously Presented) The catheter insertion device of claim 11, wherein the needle guard is made from a metal material.

21. (Previously Presented) The device according to claim 1, further comprising a valve actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section, with two legs extending proximally therefrom, the two proximally extending legs defining a space therebetween configured for receiving the needle guard element.

22. (Previously Presented) The device according to claim 21, wherein the catheter hub comprises a diameter variation on an inner circumference of the catheter hub located between a distal end and a proximal end of the valve actuating element.

23. (Previously Presented) The catheter insertion device according to claim 10, wherein the movable valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs defining a space therebetween configured to receive the needle guard element.

24. (Previously Presented) The catheter insertion device according to claim 10, wherein the catheter hub comprises a diameter variation on an inner circumference of the catheter hub located between a distal end and a proximal end of the valve actuating element when in the ready position.

25. (Previously Presented) The catheter insertion device according to claim 11, wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs defining a space therebetween configured for receiving the needle guard element therebetween.

26. (Previously Presented) The catheter insertion device according to claim 11, wherein the catheter hub comprises a diameter variation on an inner circumference of the catheter hub located between a distal end and a proximal end of the valve actuating element when in the ready position.

EVIDENCE APPENDIX

Appellants have not submitted any evidence pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132. Appellants are unaware of any evidence entered by the Examiner.

RELATED PROCEEDINGS APPENDIX

Appellants are unaware of any related proceedings.